

# STANDARD OPERATING PROCEDURE

## STH Researcher

### Project Registration with STH NHS Foundation Trust

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<i>Approved by</i>	<i>Research Manager (DP)</i>

## **Project Registration with Sheffield Teaching Hospitals NHS Foundation Trust**

This SOP has been produced in accordance with the Department of Health's Research Governance Framework 2005. This SOP will outline the procedure for registering all research studies undertaken at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

### **Background**

The DH Research Governance Framework 2005 requires that all research must be registered with the Research Department of any NHS Trust in which they will take place. The process of registration enables the Research Department to track each study and ensure that Research Governance requirements are fulfilled to permit authorisation and commencement within STH.

### **Definition**

Project Registration is the first step in the Research Governance Authorisation process, without which no study on STH premises, involving STH patients, staff or their data may begin. Project Registration provides the investigator with access to support from the Research Department in the stages involved in obtaining the approvals and agreements necessary for authorisation, ensuring that Research Governance requirements are met.

### **Procedure**

1. The Project Registration process requires the investigator to complete an STH Project Registration Form and submit it to the Research Governance Facilitator (RGF) for registration.
  - 1.1. A Project Registration Form may be obtained from the Clinical Research Office website <http://www.sheffieldclinicalresearch.org/clinical-research-office/registering-your-project>.
  - 1.2. The investigator or delegated member of his/her research team completes and sends the Project Registration Form via email to the RGF.
2. The details required for registration are listed on the Project Registration Form and the investigator is required to complete all fields, based on the intended research project.
  - 2.1. The Project Registration Form is intended to create an overview of the proposed research project to assist the Research Department in assessing its individual research governance requirements.
  - 2.2. Submission of an incomplete Project Registration Form will result in a delay to the project registration process.
  - 2.3. The investigator is advised to consider their project details carefully to avoid errors in project information.
3. **Project Registration Form: Full Title of Project**

The investigator completes this field by entering the full title of the study, avoiding shortened titles or acronyms.
4. **Project Registration Form: STH Principal Investigator (PI)**

The Research Department needs to know who will be conducting the project within STH.

  - 4.1. If the research project is being initiated by an External Investigator, who does not hold an STH Substantive or Honorary Clinical Contract, then the details of their STH Local Contact must be included as the STH PI. Advice regarding Local Contacts may be sought from the RGF or directorate page: <http://www.sheffieldclinicalresearch.org/clinical-research-activity/sheffield-teaching-hospitals>
  - 4.2. If the research project forms part of an educational course, then the details of the Clinical or Academic Supervisor from within STH NHS FT must be included as the PI. If the Student Investigator's supervisor does not hold an STH NHS FT Substantive or Honorary Clinical Contract, then an STH Local Contact must be used instead. The student must not be identified as the project's STH PI.
5. **Project Registration Form: Funding Organisation**

The investigator includes the details of the Funding Organisation (and specific scheme, if applicable) and Funding Status. If there is no funding available to conduct the research project, then the investigator must indicate this.

**6. Project Registration Form: Sponsor Organisation**

The investigator indicates the organisation that will be sponsoring the project. This must not be an individual. If the sponsor is not yet known, the investigator must indicate this.

**7. Project Registration Form: STH Participation**

The investigator chooses an option appropriate to the participation of STH NHS FT in the project.

- 7.1. The investigator indicates if the project is multi-centred or not and whether STH is the project's Lead Site. The Lead Site is defined as the organisation from which the Chief Investigator initiates and conducts the research project.
- 7.2. The investigator may also indicate if STH is being used only as a Patient Identification Centre (PIC site).

**8. Project Registration Form: Project Type**

The investigator ticks the box relevant to the nature of the project's activities, using the definitions provided in Question 2 at <https://www.myresearchproject.org.uk/Help/lrasFilterGuidance.aspx>

**9. Project Registration Form: Registration Contact Details**

The investigator completes this section by indicating which members of the research team need to be copied into the Confirmation Memo at the time of registration.

- 9.1. Please be aware that the Confirmation Memo will automatically be addressed and sent to the STH PI, the CRO Coordinator and Directorate Research Coordinator, if applicable. The investigator is advised that the person identified as the STH Local Contact or the STH Supervisor will be referred to as the STH Principal Investigator in the Confirmation Memo.

- 10. The **Confirmation Memo** contains brief information regarding the next stages of the Research Governance Authorisation process at STH NHS FT. The STH Project Number and the details of the CRO and Directorate Coordinator (if applicable) are also displayed here. The investigator is requested to check the project details in the Memo and contact the RGF if any errors are found.

The CRO Coordinator is the investigator's point of contact for queries, advice and authorisation of their registered project. The investigator is encouraged to make contact with the CRO Coordinator to schedule a set-up meeting to discuss next steps.

	Document	Website	RMS	Created
1	Project Registration Form	Yes	No	GK
2	Project Registration Memo	No	Yes	GK